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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,666	10/17/2003	Graziano Castaldi	2503-1070	8280

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EXAMINER

HUANG, EVELYN MEI

ART UNIT PAPER NUMBER

1625

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

645

Office Action Summary

Application No.

10/686,666

Applicant(s)

CASTALDI ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-7 are pending.

Election/Restrictions

2. In response to the restriction requirement mailed on 6-25-2004, Applicants have elected without traverse the Group I invention, claims 1-4, 6-7. Claim 5 of Group II invention is withdrawn from further consideration as being drawn to the non-elected invention.

Priority

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Italy on 10-21-2002. It is noted, however, that applicant has not filed a certified copy of the application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Aubert (4529596, PTO-1449). The highly purified clopidogrel of Example 1 (column 3) is encompassed by the instant claim, regardless of its process of making.
6. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Badore (4847265, PTO-1449). The highly purified clopidogrel of Example 1c (column 6) and clopidogrel

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hemisulfate of Example 1e (column 6) are encompassed by the instant claim, regardless of their process of making.

7. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Bousquet (WO 99/18100, cited in the search report, equivalent to 6573381, PTO-1449). The highly purified clopidogrel of Example 14 and clopidogrel hemisulfate of Example 15 are encompassed by the instant claim, regardless of their process of making.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aubert (4529596, PTO-1449) or Badore (4847265, PTO-1449) or Bousquet (6573381, PTO-1449, equivalent to WO 99/18110) in view of Berge (Journal of Pharmaceutical Sciences. 1977, pages 1-19) and/or Barth (6028084).

Clopidogrel is described by Aubert (Example 1), Badore (Example 1c) and Bousquet (Example 14). Aubert generically teaches that the crystalline clopidogrel may be in the pharmaceutically acceptable salt form (column 1, lines 42-51. A crystalline clopidogrel hemisulfate is described by Badore (Example 1e) and Bousquet (Example 15).

The instant differs from the prior art clopidogrel hemisulfate in being a clopidogrel alkyl sulfate.

Berge teaches that hemisulfate is a non-FDA approved commercially marketed salt (page 1, Table II) whereas methylsulfate is a FDA approved commercially marketed salt (page 2, Table I). Barth also expressly teaches that methylsulfate is a pharmaceutically acceptable salt (column 2, lines 37-40).

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At the time of the invention, one of ordinary skill in the art would be motivated to replace the non-FDA approved hemisulfate salt of Badore or Bousquet with the FDA approved methylsulfate as taught by Berge and Barth to arrive at the instant invention.

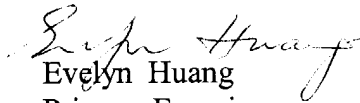
Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Evelyn Huang
Primary Examiner
Art Unit 1625